

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

LAWRENCE CHICHILA and
PAMELA CHICHILA,

Plaintiffs,

vs.

No.
Hon.

BAXTER HEALTHCARE CORPORATION,
a foreign corporation, and BAXTER
INTERNATIONAL, INC., a foreign
corporation,

Defendants.

COMPLAINT AND JURY DEMAND

Plaintiffs, LAWRENCE CHICHILA, and PAMELA CHICHILA, by and through their attorneys, MUELLER LAW FIRM, by Wolfgang Mueller, hereby complain against the Defendants, BAXTER HEALTHCARE CORPORATION, a foreign corporation, and BAXTER INTERNATIONAL, INC., a foreign corporation (collectively “BAXTER”), in a civil action, stating unto this Court as follows:

1. Plaintiffs, LAWRENCE CHICHILA and PAMELA CHICHILA, are citizens of the State of Michigan, residing in Livonia, Michigan, within the Eastern District of Michigan.

2. Defendant, BAXTER HEALTHCARE CORPORATION, a subsidiary of BAXTER INTERNATIONAL, INC., is and was at all times, a Delaware citizen, it being a registered Delaware corporation whose corporate headquarters and principal place of business is One Baxter Parkway, Deerfield, IL 60015, and conducts business in the State of Michigan.

3. Defendant, BAXTER INTERNATIONAL, INC., is and was at all times, a Delaware citizen, it being a registered Delaware corporation whose corporate headquarters and principal place of business is One Baxter Parkway, Deerfield, IL 60015, and conducts business in the State of Michigan.

4. Jurisdiction is founded upon the diversity of citizenship of the parties pursuant to 28 USC §1332 and damages which exceed \$75,000.00, exclusive of interest and costs.

5. Venue is proper in this Court, pursuant to 28 USC §1391, as Defendant does business in this District, and the incident which forms the basis of this claim occurred within this district, specifically in Wayne County, Michigan.

GENERAL ALLEGATIONS

6. BAXTER is a manufacturer and distributor of medical products, including Baxter MiniCaps with povidone-iodine solution, either directly or indirectly, to customers throughout the United States, including Lawrence Chichila.

7. BAXTER manufactured the Baxter MiniCap (“MiniCap”) for the

benefit for patients with kidney disease. The product was approved by the Food & Drug Administration (“FDA”), via its 510(k) process, on or about January 29, 1990.

8. The MiniCap is designed and intended to be used as an accessory during the peritoneal dialysis process.

9. The MiniCap contains a plastic cap which contains a povidone-iodine soaked sponge (“sponge”), and isolates the connector of the solution transfer set used during the peritoneal dialysis process.

10. The sponge is used to disinfect the mating surface between the MiniCap and the solution transfer set.

11. Based upon information and belief, Defendants were aware that use of their defectively manufactured MiniCap may result in peritonitis, an inflammation of the membrane lining the abdominal wall and covering the abdominal organs.

12. Peritonitis is caused by an infection from bacteria or fungi, and can spread into the blood, causing sepsis, and into other organs, leading to a life-threatening or fatal infection throughout the body.

13. Plaintiff, Lawrence Chichila, has suffered from end-stage kidney disease since June of 2012. As such, he was trained to perform at-home dialysis and used the MiniCaps as part of the 3X/day peritoneal dialysis process.

14. Based on his peritoneal dialysis schedule, Plaintiff uses three MiniCaps each day.

15. Plaintiff receives a monthly shipment of peritoneal dialysis supplies from BAXTER. The monthly supplies include MiniCaps, in boxes containing 60 MiniCaps per box.

16. On August 14, 2014, Plaintiff received a monthly supply of MiniCaps, Lot # GD897165, Exp. 12/2015.

17. On or about August 27, 2014, Plaintiff began experiencing severe abdominal pain.

18. On August 28, 2014, Plaintiff was taken to University of Michigan Hospital in Ann Arbor, Michigan.

19. University of Michigan doctors diagnosed Plaintiff's condition as staph-aureus peritonitis.

20. Plaintiff was hospitalized from August 28 to September 5, 2014, during which time he underwent surgical removal of a catheter and insertion of a stent for hemo-dialysis. Plaintiff was again hospitalized from September 11 to September 20, 2014. On December 19, 2014, Plaintiff was hospitalized once again for surgery to insert a new peritoneal catheter.

21. While hospitalized, and as a direct result of the infection, Plaintiff suffered from low blood pressure, "a-fib", and small bowel obstruction.

22. On January 27, 2015, BAXTER sent an "Urgent Product Recall" notice, stating that it was voluntarily recalling eight lots of MiniCaps, including Lot #

GD897165. The recall covered a total of 4.4 million MiniCaps, because “*Baxter received complaints indicating that the sponge of the MiniCap was fully separated from the cap, partially protruding from the cap, or missing.*” The recall notice also stated that the defect “*may increase the risk of peritonitis.*”

23. On March 13, 2015, the FDA issued a Class 2 recall of the affected lots of the MiniCap.

24. As a direct and proximate result of Defendant’s negligence, set forth below, Plaintiff, LAWRENCE CHICHILA, suffered the following injuries and damages:

- a. Severe peritonitis, requiring surgery to remove his catheter;
- b. Tremendous physical pain and suffering;
- c. Tremendous emotional distress;
- d. Inability to enjoy activities of daily living as before;
- e. Significant humiliation and embarrassment;
- f. Significant medical expenses from the hospitalization;
- g. Out-of-pocket expenses;
- h. Other economic and non-economic damages which are ongoing and will be permanent.

25. As a direct and proximate result of Defendant’s negligence, Plaintiff, PAMELA CHICHILA, suffered a loss of society, companionship, and consortium with her husband, LAWRENCE CHICHILA.

COUNT I
NEGLIGENCE OF DEFENDANT, BAXTER

26. Plaintiffs incorporate by reference all previous paragraphs as though fully restated herein.

27. At all times relevant to this action and during the time the subject product was designed, developed, tested, and manufactured, Defendant, BAXTER, was under a duty to use reasonable care in the design, manufacture, and assembly of the subject BAXTER MiniCaps, to eliminate any unreasonable risk of foreseeable injury. BAXTER was under the additional duty to manufacture the MiniCaps to eliminate safety defects which would render the product unfit for its intended, foreseeable uses and foreseeable misuse.

28. Despite the duties set forth above, BAXTER was negligent in at least the following respects:

- a. Negligently failing to design, develop, test, manufacture, and assemble the MiniCap lots to prevent failure of the product to provide a sterile barrier protection at the end of the transfer set, which BAXTER knew could lead to the development of peritonitis;
- b. Negligently failing to implement basic manufacturing quality control processes to eliminate the incidence of partially protruding, separated, or missing caps, which BAXTER knew could lead to the development of peritonitis;
- c. Negligently failing to recall MiniCaps when it first obtained notice of partially protruding, separated, or missing caps, which BAXTER knew could lead to the development of peritonitis in its physically-compromised patients;

- d. Negligently failing to warn customers, including Plaintiff, that partially protruding, separated, or missing caps, could be present in its manufactured lots, as BAXTER knew the defect could lead to the development of peritonitis;
- e. Other acts of negligence that will be discovered through the course of this litigation.

Accordingly, Plaintiffs respectfully request that the trier of fact award all damages allowed under Michigan law. Plaintiffs also request that this court award pre-judgment interest, costs and attorney fees.

COUNT II
GROSS NEGLIGENCE OF BAXTER

29. Plaintiffs incorporate by reference all previous paragraphs as though fully restated herein.

30. During the time of the design, manufacture, and assembly of the subject product, BAXTER had actual knowledge of facts, including FDA complaints, that would put a manufacturer on inquiry of the potential for product defects with its MiniCaps causing peritonitis.

31. During the time of the design, manufacture and sale of the subject product, BAXTER had actual knowledge of the defective conditions set forth above, and that there was a substantial likelihood that the defect would cause serious injuries to physically-compromised individuals, including the same type of injuries in this case. Despite such knowledge, BAXTER willfully disregarded that knowledge in

the manufacture or distribution of the product.

32. Based on BAXTER's actual knowledge, MCL §600.2946(4), 600.2946(a), 600.2947(1)-(4), and, 600.2948(2), do not apply, pursuant to MCL §600.2949(a).

33. Given the circumstances in this case, including BAXTER's knowledge of the foreseeability of customers developing fatal peritonitis, and considering the inability of Plaintiff to protect himself under these circumstances, BAXTER's conduct constitutes "gross negligence," which is defined as "*conduct so reckless as to demonstrate a substantial lack of concern for whether injury results.*" MCL 600.2945.

Accordingly, Plaintiffs respectfully request that the trier of fact award all damages allowed under Michigan law. Plaintiffs also request that this court award pre-judgment interest, costs and attorney fees.

MUELLER LAW FIRM

s/Wolfgang Mueller
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Dated: April 3, 2019

DEMAND FOR JURY TRIAL

Plaintiffs, by and through their attorneys, Mueller Law Firm, hereby demand a jury trial in the above-captioned cause of action.

MUELLER LAW FIRM

s/Wolfgang Mueller _____

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Dated: April 3, 2019